

REMARKS

Claims 1-26 and 44-47 are pending in this application. Claims 27-43 have been canceled without prejudice or disclaimer. Claims 1-26 have been amended. Claims 44-47 have been newly added.

Claims 27-43 have been canceled without prejudice or disclaimer, and claims 1-26 have been amended, for the sole reason of advancing prosecution. Applicants, by canceling or amending any claims herein, make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert any of the claims canceled herein or the original claim scope of any claim amended herein, in a continuing application.

Claim 1 has been amended to recite “[an] apparatus for freezing a biological sample in a flexible container, the apparatus comprising: a cooling axis; at least one set of two cooling plates with inner surfaces positioned along the cooling axis, each at least one set of two cooling plates comprising a first longitudinal plate dimension perpendicular to the cooling axis, and a second horizontal plate dimension parallel to the cooling axis; a passage defined between the inner surfaces of the plates, the passage comprising an inner width that conforms to an outer width of the container, and a height no larger than the first longitudinal plate dimension; and a motion unit adapted to move the container through the passage along the cooling axis such that the sample is cooled by conduction from direct contact between the container and the inner surfaces of the plates.” Support for claim 1, as amended, can be found throughout the specification and claims as originally filed.

Claims 2-26 have been amended to be placed in a form consistent with US claim format. Support for the amendments to claims 2-26 can be found throughout the specification and claims as originally filed.

Claims 44-47 has been newly added. New claim 44 is directed to the “apparatus according to claim 1, wherein when the container is in the apparatus, the biological sample is disposed in the container such that the biological sample remains below the height of the passage.” New claim 45 is directed to the “apparatus according to claim 1, wherein the biological sample comprises red blood cells.” New claim 46 is directed to the apparatus according to claim 1, wherein the container is a blood bag.” New claim 47 is directed to the “apparatus according to claim 1, wherein the container has a length twenty times larger than the width of the container.” Support for newly added claims 44-47 can be found throughout the specification and claims as originally filed.

The abstract has also been amended to conform with US practice. As amended, the abstract does not recite the term “comprising” and is less than 150 words in length.

No new matter has been added.

In view of the remarks set forth below, further and favorable consideration is respectfully requested.

I. Interview

Applicants thank Examiner Koagel and Supervisory Examiner Tyler for conducting an in person interview with Applicants’ undersigned representative on October 28, 2009 at the United States Patent and Trademark Office. During the interview, the nature of the subject matter was discussed. For example, Applicants’

representative distinguished the present subject matter from that in the cited art by explaining that the container may be a flexible container for holding a biological sample such as a blood bag, or the like. Additionally, Applicants' representative noted that there is no motivation to modify the teachings of the references.

II. At page 2 of the Official Action, the specification is objected to.

The Examiner asserts that the abstract is not in proper form because the term "comprising" is used therein.

Applicants respectfully submit that the abstract has been amended herein. The amended abstract no longer recites the term "comprising." Applicants submit that the amended abstract is in full compliance with section 608.01(b) of the MPEP. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

III. At page 2 of the Official Action, claims 4, 14, 28 and 35 are objected to.

The Examiner indicates that claims 4, 14, 28 and 35 are in improper form due to the reasons discussed in the Official Action. Applicants note that claims 28 and 35 have been cancelled without prejudice or disclaimer. Thus, the objection to claims 28 and 35 has been obviated. In addition, Applicants submit that claims 4 and 14 have been amended to be placed in a format consistent with proper US practice. In view of the cancelation of claim 28 and 35 and the amendments to claims 4 and 14, Applicants respectfully request reconsideration and withdrawal of the aforementioned objections.

IV. At page 2 of the Official Action, claims 1-43 have been rejected under 35 USC § 103(a) as being unpatentable over Arav (US Patent No. 5,873,254) in view of Polk (US Patent No. 3,074,247).

The Examiner asserts that it would have been obvious to modify the apparatus described by Arav with the passage and container thickness described by Polk to obtain the claimed subject matter.

Applicants note that claims 27-43 have been cancelled without prejudice or disclaimer. Accordingly, the rejection of claims 27-43 has been rendered moot.

In view of the remarks set forth herein, the rejection of claim 1-26 is respectfully traversed.

To establish a *prima facie* case of obviousness, the Examiner must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, 550 U.S. 398 at 417.) Second, the proposed modification of the prior art

must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Regarding motivation to modify properly combined references, **MPEP 2143** states that where the prior art conflicts, all teachings must be considered and that the fact that references can be combined or modified is not sufficient to establish *prima facie* obviousness. **MPEP 2143** further states that there must be some suggestion or motivation to modify the references, and there must be a reasonable expectation of success.

MPEP 2143.01 states that a proposed modification cannot render the prior art unsatisfactory for its intended purpose. If it does, then there is no suggestion or motivation to make the proposed modification. Further, the proposed modification cannot change the principle operation of a reference.

It is submitted that a *prima facie* case of obviousness has not been established because nothing in the applied references, whether taken alone or in combination, teach or suggest all of the elements of the present claims, as required by *In re Wilson*. Further, assuming *arguendo* that all of the elements were taught or suggested, Applicants respectfully submit that there is no motivation to modify the cited references to arrive at the presently claimed subject matter.

Independent claim 1 is directed to an apparatus for freezing a biological sample in a flexible container, the apparatus comprising: a cooling axis; at least one set of two

cooling plates with inner surfaces positioned along the cooling axis, each at least one set of two cooling plates comprising a first longitudinal plate dimension perpendicular to the cooling axis, and a second horizontal plate dimension parallel to the cooling axis; a passage defined between the inner surfaces of the plates, the passage comprising an inner width that conforms to an outer width of the container, and a height no larger than the first longitudinal plate dimension; and a motion unit adapted to move the container through the passage along the cooling axis such that the sample is cooled by conduction from direct contact between the container and the inner surfaces of the plates. Claims 2-26 each depend, either directly or indirectly, from claim 1.

Applicants note that the presently claimed subject matter is directed to an apparatus for freezing a flexible container containing a biological sample. According to the presently claimed subject matter, the apparatus includes at least one set of two cooling plates that form a passage in which the container is moved through to facilitate cooling. The apparatus is adapted such that outer surfaces of the container are in direct contact with the inner surfaces the cooling plates so that cooling by conduction occurs.

As provided at page 5 of the present specification, “[t]he container C is preferably flexible, so as to allow even distribution of the sample against both inner surfaces 13.” (Emphasis Added).

The specification further provides that:

[f]reezing a biological sample using a freezing apparatus as described above has the advantage that a relatively narrow yet optionally tall container can be used, and still achieve controlled freezing of a large biological sample in a directional manner without extensive damage to cells. For example, a container with dimensions of 10 mm width × 200 mm height × 300 mm depth can

be used to freeze a 600 ml sample using the freezing apparatus as seen in Fig. 1. See the present specification at page 8.

In addition, Applicants note that the specification provides that:

[s]ince the plates **12** are adapted to cool by conduction, it is important to maintain direct contact between them and the container **C**. There may therefore be provided a mechanism for ensuring that the plates maintain a tight contact even during expanding and contracting of the biological sample within a flexible container. The plates **12**, at least on one side, may be mounted on springs in order to automatically adjust to the varying width of the container **C** and maintain direct contact. Alternatively, the plates **12** themselves may be constructed so that the inner surfaces **13** thereof are biased on springs toward the direction of the passage **14**. See the specification at page at the paragraph bridging pages 6 and 7.

In contrast to the presently claimed subject matter Arav is directed to device having a laterally varying thermal gradient and which a mechanism for moving the sample along the thermal gradient at a controlled rate of speed. See Arav at the abstract. The *sample in Arav is contained in a straw* configured for biological material. As known to those skilled in the art *the straws used by Arav are not suitable for large samples and are not flexible*. According to Arav, the straws are placed on a thermally conductive sled, which is moved through a tunnel that is preferably of a rectangle cross section that runs through the blocks. The blocks according to Arav are fixed in place, and *the straws cannot be in direct contact with any the inner surface of the blocks*.

Therefore, unlike the presently claimed subject matter Arav does not teach or suggest an apparatus for cooling a biological sample in a flexible container in which the container is in direct contact with cooling blocks and the passage that the container passes through is adapted to conform with the container, as presently claimed.

Accordingly, Applicants submit that Arav does not teach or suggest every element of the present claims.

Polk does not remedy the deficiencies of Arav. In contrast to the pending subject matter, Polk is directed to a freezing apparatus which aims to reduce frosting during loading and removal of packages vertically disposed between cooling plates. According to Polk, the packages, once in place, remain static at their position.

Like Arav, Polk does not teach or suggest an apparatus for cooling a biological sample in a flexible container that is in direct contact with cooling blocks while it moves along a cooling axis and that has a passage adapted to conform to the width of the container, as presently claimed. Therefore, whether taken alone or in combination neither Arav nor Polk teach each and every element of claims 1-26, as required to establish a *prima facie* case of obviousness.

In addition to not teaching or suggesting every element of the claimed subject matter, Applicants submit that there would be no motivation to modify the device described by Arav with the teachings of Polk because doing so would destroy the principle mode of operation of Arav. In this regard, Applicants note that the device of Arav requires movement to cool. Modifying the device of Arav to cool a container in a fixed position would destroy its principle of operation. Further, Applicants note that the straw described by Arav is not suited to be in direct contact with cooling plates because the sample within the straw would not freeze as described by Arav. Accordingly, modifying the cited references to arrive at the presently claimed subject matter would change the principle of operation of the references.

Therefore, Applicants submit that none of the cited references, or render the presently claimed subject matter obvious, within the meaning of either of 35 USC § 103(a). Thus, the Examiner is respectfully requested to withdraw this rejection of claims 1-26.

V. New Claims 44-47

Claims 44-47 have been newly added. New claim 44 is directed to the “apparatus according to claim 1, wherein when the container is in the apparatus, the biological sample is disposed in the container such that the biological sample remains below the height of the passage.” New claim 45 is directed to the “apparatus according to claim 1, wherein the biological sample comprises red blood cells.” New claim 46 is directed to the apparatus according to claim 1, wherein the container is a blood bag.” New claim 47 is directed to the “apparatus according to claim 1, wherein the container has a length twenty times larger than the width of the container.”

Applicants respectfully submit that new claims 44-47 are both novel and non-obvious. Accordingly, Applicants respectfully request an indication that all of the pending claims are now allowable.

CONCLUSION

In view of the foregoing, Applicants submit that the application is in condition for immediate allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

THE NATH LAW GROUP

A handwritten signature in black ink, appearing to be 'S. Hopkins', written over a horizontal line.

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Date: December 8, 2009
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